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**Filed** : October 9, 2003

### **REMARKS**

The foregoing amendments and the following remarks are responsive to the July 28, 2005 Office Action. Claims 22, 27, 31-36, 42, and 43 are cancelled without prejudice, Claims 1, 26, 30, 37, 39, 44, 47, and 50-53 are amended, and Claims 2-21, 23-26, 28, 29, 38, 40, 41, 45, 46, 48, 49, and 54-66 remain as originally filed. Thus, Claims 1-21, 23-26, 28-30, 37-41, and 44-66 are presented for further consideration. Please enter the amendments and reconsider the claims in view of the following remarks.

#### **Response to Objections to Amendments filed December 11, 2003, February 2, 2004, and February 9, 2004 Under 35 U.S.C. § 132(a)**

In the July 28, 2005 Office Action, the Examiner rejects the amendments filed December 11, 2003, February 2, 2004, and February 9, 2004 under 35 U.S.C. § 132(a) as introducing new matter into the disclosure. Specifically, the Examiner rejects all amendments to the priority claim to "U.S. Provisional Application No. 60/504,142."

Applicants respectfully submit that the amendments to the priority claim filed December 11, 2003, February 2, 2004, and February 9, 2004 are allowable under 37 CFR § 1.78(a)(2)(ii) because they were submitted within four months of the filing date of the present application (i.e. within four months of October 9, 2003). Section 1.78(a)(2)(ii) states that priority references must be submitted "within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application." In the present case, since the actual filing date is October 9, 2003, amendments filed on or before February 9, 2004 are allowable. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of the amendments to the priority claim made on December 11, 2003, February 2, 2004, and February 9, 2004.

In addition, Applicants respectfully submit that the amendments to the priority claim do not add new matter to the present application, so the amendments are allowable under M.P.E.P. § 201.11(III)(F). Section 201.11(III)(F) states that "[w]hen a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application unless an incorporation by reference statement of the prior application was presented upon filing of the application." Because the amendments do not include an incorporation by reference statement, Applicants submit that the amendments do not

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add new matter to the present application. Applicants respectfully request the Examiner to withdraw the rejection of the amendments made on December 11, 2003, February 2, 2004, and February 9, 2004.

**Response to Rejection of Claims 1-25 Under 35 U.S.C. § 101**

In the July 28, 2005 Office Action, the Examiner rejects Claims 1-25 under 35 U.S.C. § 101 because the “claimed invention is directed to non-statutory subject matter” due to the “positive recitation of ‘the scalp.’”

Applicants have cancelled Claim 22 without prejudice and have amended Claim 1. Applicants respectfully submit that “the scalp” is not a component of the therapy apparatus claimed in any of Claims 1-21 and 23-25. For example, the term “the scalp” is merely used in amended Claim 1 to recite the position of the element as “interposed between the light source and the patient’s scalp” and to recite various features of the element as being “adapted to inhibit temperature increases at the scalp,” “adapted to apply pressure to at least a portion of the scalp,” and “blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp.” Because the scalp is not a component of the therapy apparatus claimed in Claims 1-21 and 23-25, Applicants respectfully request the Examiner to withdraw the rejection of Claims 1-21 and 23-25 and to pass these claims to allowance.

**Response to Rejection of Claims 47-49 Under 35 U.S.C. § 112, Second Paragraph**

In the July 28, 2005 Office Action, the Examiner rejects Claims 47-49 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Office Action states that “exactly what is intended by the term ‘electromagnetic energy’ is unclear, as applicant seems to feel that this term encompasses magnetic energy alone.”

Applicants respectfully note that Claims 47-49 do not use the term “electromagnetic energy.” Rather, Claims 47-49 use the term “electromagnetic field,” which encompasses a magnetic field alone, an electric field alone, or both an electric field and a magnetic field, and is not indefinite. Applicants respectfully request that the Examiner withdraw the rejection of Claims 47-49 and pass these claims to allowance.

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**Response to Rejection of Claims 1-6, 8-11, 14, 19, 22, and 24-32 Under 35 U.S.C. § 102(b)**

In the July 28, 2005 Office Action, the Examiner rejects Claims 1-6, 8-11, 14, 19, 22, and 24-32 as being anticipated by U.S. Patent No. 5,150,704 issued to Tatebayashi et al. ("Tatebayashi").

Claims 1-6, 8-11, 14, 19, 22, 24, and 25

Applicants respectfully submit that Tatebayashi does not teach or suggest every element of amended Claim 1, and therefore fails to anticipate amended Claim 1. For example, Tatebayashi does not teach or suggest an element that "is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp," as recited in amended Claim 1. Therefore, amended Claim 1 is patentably distinguished over Tatebayashi. Each of Claims 2-6, 8-11, 14, 19, 24, and 25 directly or indirectly depends from amended Claim 1, so each of Claims 2-6, 8-11, 14, 19, 24, and 25 includes all the limitations of amended Claim 1, as well as other limitations of particular utility. Therefore, each of Claims 2-6, 8-11, 14, 19, 24, and 25 is also patentably distinguished over Tatebayashi. Claim 22 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 1-6, 8-11, 14, 19, 24, and 25 and to pass these claims to allowance.

Claims 26-29

Applicants respectfully submit that Tatebayashi does not teach or suggest every element of amended Claim 26, and therefore fails to anticipate amended Claim 26. For example, Tatebayashi does not teach or suggest a "material adapted to contact the head and to apply pressure to at least the irradiated portion of the patient's head, thereby blanching the irradiated portion," as recited in amended Claim 26. Therefore, amended Claim 26 is patentably distinguished over Tatebayashi. Each of Claims 28 and 29 directly or indirectly depends from amended Claim 26, so each of Claims 28 and 29 includes all the limitations of amended Claim 26, as well as other limitations of particular utility. Therefore, each of Claims 28 and 29 is also patentably distinguished over Tatebayashi. Claim 27 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 26, 28, and 29 and to pass these claims to allowance.

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Claim 30

Applicants respectfully submit that Tatebayashi does not teach or suggest every element of amended Claim 30, and therefore fails to anticipate amended Claim 30. For example, Tatebayashi does not teach or suggest an element that “is adapted to apply pressure to at least a portion of the scalp to blanch the portion of the scalp,” as recited in amended Claim 30. Therefore, amended Claim 30 is patentably distinguished over Tatebayashi. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claim 30 and to pass this claim to allowance.

Claims 31 and 32

Claims 31 and 32 are cancelled without prejudice.

**Response to Rejection of Claims 1-10, 14-17, 19, 20, 22, and 24-30 Under 35 U.S.C. § 102(b)**

In the July 28, 2005 Office Action, the Examiner rejects Claims 1-10, 14-17, 19, 20, 22, and 24-30 as being anticipated by U.S. Patent No. 5,282,797 issued to Chess (“Chess”).

Claims 1-10, 14-17, 19, 20, 22, 24, and 25

Applicants respectfully submit that Chess does not teach or suggest every element of amended Claim 1, and therefore fails to anticipate amended Claim 1. For example, Chess does not teach or suggest an element that “is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp,” as recited in amended Claim 1. Therefore, amended Claim 1 is patentably distinguished over Chess. Each of Claims 2-10, 14-17, 19, 20, 24, and 25 directly or indirectly depends from amended Claim 1, so each of Claims 2-10, 14-17, 19, 20, 24, and 25 includes all the limitations of amended Claim 1, as well as other limitations of particular utility. Therefore, each of Claims 2-10, 14-17, 19, 20, 24, and 25 is also patentably distinguished over Chess. Claim 22 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 1-10, 14-17, 19, 20, 24, and 25 and to pass these claims to allowance.

Claims 26-29

Applicants respectfully submit that Chess does not teach or suggest every element of amended Claim 26, and therefore fails to anticipate amended Claim 26. For example, Chess does not teach or suggest a “material adapted to contact the head and to apply pressure to at least the

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irradiated portion of the patient's head, thereby blanching the irradiated portion," as recited in amended Claim 26. Therefore, amended Claim 26 is patentably distinguished over Chess. Each of Claims 28 and 29 directly or indirectly depends from amended Claim 26, so each of Claims 28 and 29 includes all the limitations of amended Claim 26, as well as other limitations of particular utility. Therefore, each of Claims 28 and 29 is also patentably distinguished over Chess. Claim 27 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 26, 28, and 29 and to pass these claims to allowance.

Claim 30

Applicants respectfully submit that Chess does not teach or suggest every element of amended Claim 30, and therefore fails to anticipate amended Claim 30. For example, Chess does not teach or suggest an element that "is adapted to apply pressure to at least a portion of the scalp to blanch the portion of the scalp," as recited in amended Claim 30. Therefore, amended Claim 30 is patentably distinguished over Chess. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claim 30 and to pass this claim to allowance.

**Response to Rejection of Claims 35 and 36 Under 35 U.S.C. § 102(e)**

In the July 28, 2005 Office Action, the Examiner rejects Claims 35 and 36 as being anticipated by U.S. Patent No. 6,443,974 issued to Oron et al. ("Oron I"). Claims 35 and 36 are cancelled without prejudice.

**Response to Rejection of Claims 1-6, 8-10, 14, 19, 22-38, 44-46, 51-54, and 57-59 Under 35 U.S.C. § 102(b)**

In the July 28, 2005 Office Action, the Examiner rejects 1-6, 8-10, 14, 19, 22-38, 44-46, 51-54, and 57-59 as being anticipated by U.S. Patent No. 6,537,304 issued to Oron ("Oron II").

Claims 1-6, 8-10, 14, 19, and 22-25

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 1, and therefore fails to anticipate amended Claim 1. For example, Oron II does not teach or suggest an element that "is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp," as recited in amended Claim 1. Therefore, amended Claim 1 is patentably distinguished over Oron II. Each of Claims 2-6, 8-10, 14, 19, and 23-25 directly or indirectly depends from amended Claim 1, so each of Claims 2-6, 8-10, 14, 19, and 23-25 includes all the

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limitations of amended Claim 1, as well as other limitations of particular utility. Therefore, each of Claims 2-6, 8-10, 14, 19, and 23-25 is also patentably distinguished over Oron II. Claim 22 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 1-6, 8-10, 14, 19, and 23-25 and to pass these claims to allowance.

Claims 26-29

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 26, and therefore fails to anticipate amended Claim 26. For example, Oron II does not teach or suggest a “material adapted to contact the head and to apply pressure to at least the irradiated portion of the patient’s head, thereby blanching the irradiated portion,” as recited in amended Claim 26. Therefore, amended Claim 26 is patentably distinguished over Oron II. Each of Claims 28 and 29 directly or indirectly depends from amended Claim 26, so each of Claims 28 and 29 includes all the limitations of amended Claim 26, as well as other limitations of particular utility. Therefore, each of Claims 28 and 29 is also patentably distinguished over Oron II. Claim 27 is cancelled without prejudice. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 26, 28, and 29 and to pass these claims to allowance.

Claim 30

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 30, and therefore fails to anticipate amended Claim 30. For example, Oron II does not teach or suggest an element that “is adapted to apply pressure to at least a portion of the scalp to blanch the portion of the scalp,” as recited in amended Claim 30. Therefore, amended Claim 30 is patentably distinguished over Oron II. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claim 30 and to pass this claim to allowance.

Claims 31-36

Claims 31-36 are cancelled without prejudice.

Claims 37 and 38

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 37, and therefore fails to anticipate amended Claim 37. For example, Oron II does not teach or suggest “directing light through a blanched portion of the scalp of a patient,” as recited in amended Claim 37. Therefore, amended Claim 37 is patentably distinguished over

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Oron II. Claim 38 directly depends from amended Claim 37, so Claim 38 includes all the limitations of amended Claim 37, as well as other limitations of particular utility. Therefore, Claim 38 is also patentably distinguished over Oron II. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 37 and 38 and to pass these claims to allowance.

Claims 44-46

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 44, and therefore fails to anticipate amended Claim 44. For example, Oron II does not teach or suggest “directing light through a blanched portion of the scalp of the patient,” as recited in amended Claim 44. Therefore, amended Claim 44 is patentably distinguished over Oron II. Each of Claims 45 and 46 directly depends from amended Claim 44, so each of Claims 45 and 46 includes all the limitations of amended Claim 44, as well as other limitations of particular utility. Therefore, each of Claims 45 and 46 is also patentably distinguished over Oron II. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 44-46 and to pass these claims to allowance.

Claims 51-54 and 57-59

Applicants respectfully submit that Oron II does not teach or suggest every element of amended Claim 51, and therefore fails to anticipate amended Claim 51. For example, Oron II does not teach or suggest “after estimating the time of the ischemic event, waiting to commence administration of a neuroprotective effective amount of light energy to the brain,” as recited in amended Claim 51. Therefore, amended Claim 51 is patentably distinguished over Oron II. Each of amended Claims 52-54 and 57-59 directly or indirectly depends from amended Claim 51, so each of amended Claims 52-54 and 57-59 includes all the limitations of amended Claim 51, as well as other limitations of particular utility. Therefore, each of amended Claims 52-54 and 57-59 is also patentably distinguished over Oron II. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 51-54 and 57-59 and to pass these claims to allowance.

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**Response to Rejection of Claims 11-13 and 21 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claims 11-13 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Chess in combination with U.S. Patent No. 5,474,528 issued to Meserol ("Meserol") and U.S. Patent No. 5,622,168 issued to Keusch et al. ("Keusch").

Applicants submit that neither Meserol nor Keusch, either alone or in combination, teaches or suggests all the limitations of amended Claim 1 which are not disclosed or suggested by Chess. For example, neither Meserol nor Keusch teaches or suggests an element that "is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp," as recited in amended Claim 1. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess in combination with Meserol and Keusch. Each of Claims 11-13 and 21 indirectly depends from amended Claim 1. Therefore, each of Claims 11-13 and 21 includes all the limitations of amended Claim 1, as well as other limitations of particular utility. Applicants therefore submit that each of Claims 11-13 and 21 is patentably distinguished over Chess in combination with Meserol and Keusch. Applicants respectfully request the Examiner to withdraw the rejection of Claims 11-13 and 21 and to pass these claims to allowance.

**Response to Rejection of Claim 18 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Chess.

Applicants submit that Chess fails to teach or suggest every element of amended Claim 1. For example, Chess does not teach or suggest an element that "is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp," as recited in amended Claim 1. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess. Claim 18 indirectly depends from amended Claim 1. Therefore, Claim 18 includes all the limitations of amended Claim 1, as well as other limitations of particular utility. Applicants submit that Claim 18 is patentably distinguished over Chess, and respectfully request the Examiner to withdraw the rejection of Claim 18 and to pass this claim to allowance.



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**Response to Rejection of Claim 21 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Chess in combination with U.S. Patent No. 5,643,334 issued to Eckhouse et al. ("Eckhouse").

Applicants submit that Eckhouse does not teach or suggest all the limitations of amended Claim 1 which are not disclosed or suggested by Chess. For example, Eckhouse does not teach or suggest an element that "is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp," as recited in amended Claim 1. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess in combination with Eckhouse. Claim 21 indirectly depends from amended Claim 1. Therefore, Claim 21 includes all the limitations of amended Claim 1, as well as other limitations of particular utility. Applicants submit that Claim 21 is patentably distinguished over Chess in combination with Eckhouse, and respectfully request the Examiner to withdraw the rejection of Claim 21 and to pass this claim to allowance.

**Response to Rejection of Claims 39-41 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claims 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Oron II in combination with U.S. Patent No. 6,045,575 issued to Rosen et al. ("Rosen").

Applicants submit that neither Oron II nor Rosen, either alone or in combination, teaches or suggests all the limitations of amended Claim 39. For example, neither Oron II nor Rosen teaches or suggests a "light-emitting blanket comprising a first side in proximity to the scalp and a second side having a reflective coating to reflect light emitted away from the scalp back towards the scalp," as recited in amended Claim 39. Therefore, Applicants submit that amended Claim 39 is patentably distinguished over Oron II in combination with Rosen. Each of Claims 40 and 41 directly depends from amended Claim 39, so each of Claims 40 and 41 includes all the limitations of amended Claim 39, as well as other limitations of particular utility. Therefore, each of Claims 40 and 41 is patentably distinguished over Oron II in combination with Rosen. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 39-41 and to pass these claims to allowance.

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**Response to Rejection of Claims 55, 56, 60, and 61-66 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claim 55, 56, 60, and 61-66 under 35 U.S.C. § 103(a) as being unpatentable over Oron II.

Applicants submit that Oron II fails to teach or suggest every element of amended Claim 51. For example, Oron II does not teach or suggest “after estimating the time of the ischemic event, waiting to commence administration of a neuroprotective effective amount of light energy to the brain,” as recited in amended Claim 51. Therefore, Applicants submit that amended Claim 51 is patentably distinguished over Oron II. Each of Claims 55, 56, 60, and 61-66 directly or indirectly depends from amended Claim 51. Therefore, each of Claims 55, 56, 60, and 61-66 includes all the limitations of amended Claim 51, as well as other limitations of particular utility. Therefore, each of Claims 55, 56, 60, and 61-66 is patentably distinguished over Oron II. Applicants therefore respectfully request the Examiner to withdraw the rejection of Claims 55, 56, 60, and 61-66 and to pass these claims to allowance.

**Response to Rejection of Claim 50 Under 35 U.S.C. § 103(a)**

In the July 28, 2005 Office Action, the Examiner rejects Claim 50 under 35 U.S.C. § 103(a) as being unpatentable over Oron II in combination with U.S. Patent No. 6,551,308 issued to Muller et al. (“Muller”), stating that “Oron teaches a method as claimed except for the electroluminescent sheet.” Applicants respectfully note that Claim 50 does not recite an electroluminescent sheet and assume that the Examiner intended to state that Oron does not recite use of ultrasonic energy. If Applicants are incorrect in this assumption, Applicants respectfully request clarification by the Examiner.

Applicants submit that neither Oron II nor Muller, either alone or in combination, teaches or suggests all the limitations of amended Claim 50. For example, neither Oron II nor Muller teaches or suggests “directing an efficacious power density of light through a blanched portion of the scalp,” as recited in amended Claim 50.

Applicants further submit that the prior art does not provide a motivation to combine Oron II with Muller because of the fundamental difference in treatment methods these patents disclose. Oron II discloses a non-invasive apparatus for treating ischemia in the brain. All embodiments disclosed in Oron II are directed to providing light to brain tissue from outside the cranium. *See, e.g.*, Oron II, col. 3, ll. 52-65. In contrast, Muller discloses an instrument for

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revascularization of muscular tissue comprising an optical fiber that must contact the tissue being treated. Muller discloses that the optical fiber transmits light and vibrates at ultrasonic speeds to perforate muscular tissue to promote vascularization. *See*, Muller, col. 1, ll. 50-61; col. 2, ll. 47-65; col. 4, ll.19-36. Modifying the disclosed method of Oron II to utilize the invasive ultrasonic technique disclosed in Muller would render the method of Oron II unsatisfactory for its intended purpose, so there is no suggestion or motivation to make the proposed modification.

For at least these reasons, Applicants submit that amended Claim 50 is patentably distinguished over Oron II in combination with Muller. Therefore, Applicants respectfully request the Examiner to withdraw the rejection of Claim 50 and to pass this claim to allowance

**Response to Rejection of Claims 42 and 43 Under 35 U.S.C. § 103(a)**

Claims 42 and 43 are cancelled without prejudice.

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### Summary

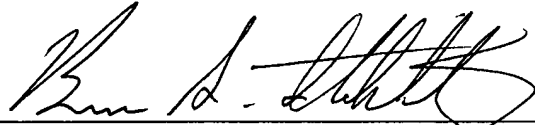
For the above-stated reasons, Applicants submit that Claims 1-21, 23-26, 28-30, 37-41, and 44-66 are in condition for allowance, and Applicants respectfully request such action.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

Dated: 11/23/05

By:

  
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